

Application No. 10/826,654  
Amendment dated June 16, 2008  
Reply to Office Action issued December 14, 2007

Docket No.: P-6041 020187.0208PTUS

**AMENDMENT TO THE DRAWINGS**

Amended drawing figure 13 is attached following page 36 of this paper as Replacement Sheet Figure 13.

Attachment: Replacement Sheet

Application No. 10/826,654  
Amendment dated June 16, 2008  
Reply to Office Action issued December 14, 2007

Docket No.: P-6041 020187.0208PTUS

### REMARKS

The Office Action mailed December 14, 2007, has been reviewed and the Office's comments have been considered. The Applicant respectfully submits this amendment and requests reconsideration of the rejection of the claims.

#### **1. Claim Amendments**

Claims 1-114 are currently pending in this Application. Claims 9, 16-19, 31-73 and 79-114 have been withdrawn due to restriction of the claims. Claims 1-8, 10-15, 20-30 and 74-78 currently are being examined. By this Amendment, Applicants have amended claims 1, 6 and 15. Support for the claim amendments can be found throughout the specification and the original claims. No new matter has been added by the amendments to the claims.

#### **2. Election/Restriction**

Applicant thanks the Examiner for reconsideration of the Restriction for election of species in the reply filed June 28, 2007, and withdrawal of the species election.

#### **3. Drawing**

The Examiner required a new Figure 13 that was clearer to read. Applicant has submitted a replacement drawing in response, and respectfully requests entry of the replacement sheet.

#### **4. Oath/Declaration**

The Examiner stated he could not locate an oath/declaration in the instant application. Applicant filed a declaration September 15, 2004, in response to the Notice of Missing Parts. Applicant is submitting a copy of the declaration filed in this instant application, along with a copy of the date-stamped postcard from the USPTO acknowledging receipt of the declaration September 20, 2004.

Application No. 10/826,654  
Amendment dated June 16, 2008  
Reply to Office Action issued December 14, 2007

Docket No.: P-6041 020187.0208PTUS

## 5. Specification

The Examiner noted that the abstract exceeded the 150 word limit. By this Amendment, Applicant has amended the abstract to 116 words. Applicant requests entry of the amended abstract.

## 6. Claim Rejections Under 35 USC §112, 2nd paragraph

The Examiner rejected claims 1-8, 10-15, and 20-30 under 35 USC §112, 2nd paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter that applicant regards as the invention. Office Action at page 3.

The Examiner asserted that claim 1 is vague and indefinite in view of the phrase "the hybrid comprises a 3' terminus of the first or second oligonucleotide moieties" in (d) of step (i) because a hybrid formed by the first portion of the first oligonucleotide moiety and the portion of the second oligonucleotide moiety must have 3' terminus of the first or second oligonucleotide moieties." Office Action at page 3. Applicant notes that the quoted element of claim 1 is step (ii) rather than step (i) (d) as stated in the Office Action. Claim 1 is amended to recite step (ii) as "forming a hybrid comprising the first portion of the first oligonucleotide moiety and the portion of the second oligonucleotide moiety, where the hybrid comprises a 3' terminus of the first or second oligonucleotide moieties that may be extended" to clarify further that the hybrid comprises a 3' terminus of the first or second oligonucleotide moieties that has an ability to extend in an amplification reaction.

The Examiner also rejected claim 6, asserting the claim is unclear whether all of the bases of the first portion of the first oligonucleotide moiety are complementary to the hybridization blocker oligonucleotide in a hybrid formed by the first oligonucleotide moiety and the

Application No. 10/826,654  
Amendment dated June 16, 2008  
Reply to Office Action issued December 14, 2007

Docket No.: P-6041 020187.0208PTUS

hybridization blocker oligonucleotide. Applicant has amended claim 6 to recite the hybridization blocker oligonucleotide contains bases that form a hybrid with the first portion of the first oligonucleotide moiety comprising all of the bases of the first portion of the first oligonucleotide moiety.

Finally, the Examiner rejected claim 15, asserting the claim is unclear what is combined with the hybridization blocker oligonucleotide. Applicant has amended claim 15 to clarify further the hybridization blocker oligonucleotide is combined to form a hybrid with the first portion of the first oligonucleotide moiety prior to combining the deblocker oligonucleotide.

Therefore, amendments to claims 1, 6 and 15 and the dependent claims 2-5, 7-8, 10-14, and 20-30 overcome the issues of indefiniteness. Applicant respectfully requests withdrawal of the rejection of 1-8, 10-15, and 20-30 under 35 USC §112, 2nd paragraph.

**7. Claim Rejections under 35 USC § 102 (e)**

The Examiner rejected claims 1-3, 6, 8, 13, 14, 21, 27, and 74-78 under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,815,164 to Kurn. The Examiner asserted "Kurn teaches a method of detecting an analyte, comprising: (i) combining: (a) an analyte (ie., the target nucleic acid sequence); (b) a first proximity member, comprising a first analyte-specific binding entity that is capable of forming a complex with the analyte and that is conjugated to a first oligonucleotide moiety comprising a first portion (ie., the first probe); (c) a second proximity member, comprising a second analyte-specific binding entity that is capable of forming a complex with the analyte and that is conjugated to a second oligonucleotide moiety comprising a portion that is capable of hybridizing to the first portion of the first oligonucleotide (ie., the second probe); (d) a hybridization blocker oligonucleotide (ie., the third probe), where the hybridization blocker oligonucleotide comprises a portion that is capable of forming a hybrid

Application No. 10/826,654  
Amendment dated June 16, 2008  
Reply to Office Action issued December 14, 2007

Docket No.: P-6041 020187.0208PTUS

with the first portion of the first oligonucleotide moiety; (ii) forming a hybrid comprising the first portion of the first oligonucleotide moiety and the portion of the second oligonucleotide moiety, where the hybrid comprises a 3' terminus of the first or second oligonucleotide moieties; (iii) extending the 3' terminus to produce an amplicon; (iv) amplifying the amplicon to produce an amplification product; and (v) detecting the amplification product; wherein detection of the amplification product allows detection of the analyte (see claim 30 in columns 40 and 41, Examples 1 and 2 in columns 34-36, and *Figure 13 with the examiner's handwritings*). Office Action at pages 4-5; emphasis added.

Applicants respectfully traverse the rejection and request reconsideration based on the following comments.

To find anticipation under 35 U.S.C. § 102, every element of the claims must be taught in a single reference. MPEP § 2131; *See, e.g., Carella v Startlight Archery and Pro Line Co.*, 804 F.2d 135, 138 (Fed. Cir. 1986). Applicant's invention of claim 1 recites a method of detecting an analyte comprising combining an analyte, first and second proximity members and a hybridization blocker, and (i) forming a hybrid comprising the first portion of the first oligonucleotide moiety and the portion of the second oligonucleotide moiety, where the hybrid comprises a 3' terminus of the first or second oligonucleotide moieties that may be extended; (ii) extending the 3' terminus to produce an amplicon; (iv) amplifying the amplicon to produce an amplification product; and (v) detecting the amplification product; wherein detection of the amplification product allows detection of the analyte. Kurn does not teach amplifying the amplicon to produce an amplification product; and detecting the amplification product; wherein detection of the amplification product allows detection of the analyte. Kurn teaches a method of detecting whether a target nucleic acid sequence is present in a sample, comprising contacting said sample with a first probe, a second probe, a third probe, and

Application No. 10/826,654  
Amendment dated June 16, 2008  
Reply to Office Action issued December 14, 2007

Docket No.: P-6041 020187.0208PTUS

a nucleotide polymerase, under conditions allowing hybridization of the first and second probes to the target nucleic acid sequence, if present, and hybridization of the first probe to the third probe, in the absence of the target nucleic acid sequence, and allowing nucleic acid polymerization. (See claim 30). Specifically in claim 30 of Kurn, in the presence of the target nucleic acid sequence, said 3' region of said first probe hybridizes to said first region of the target nucleic acid sequence and said 5' region of said second probe hybridizes to said second region of the target nucleic acid sequence; and wherein the 3' end of said second probe is extended by said nucleotide polymerase along the first probe by template switching, causing dissociation of the first and second members of the interacting label pair; whereby generation of detectable signal caused by dissociation of the interacting label pair indicates presence of the target nucleic acid sequence. Kurn teaches amplifying the target nucleic acid with the use of probes and detecting the target nucleic acid. The present invention further produces an amplicon that is amplified to produce an amplification product and detecting the amplification product, wherein detection of the amplification product allows detection of the analyte.

Figure 13 of Kurn cited by the Examiner illustrates a means of signal detection and labels Probes A, B and C in relation to the target for amplification. Where Probe B is extended in Kurn, the extension product may be considered an amplicon. Kurn teaches that the extension of Probe B displaces or blocks Probe C from its hybridization of Probe A, leading to detection of the signal for the target nucleic acid. See Column 34, line 66 through column 35, line 39. Kurn does not teach amplification of the amplicon to produce an amplification product. Moreover, Kurn does not teach detection of the amplification product to allow detection of the analyte. Kurn does not teach every element of claim 1 of the present invention.

Application No. 10/826,654  
Amendment dated June 16, 2008  
Reply to Office Action issued December 14, 2007

Docket No.: P-6041 020187.0208PTUS

Similarly for claim 74, Kurn does not teach the recited steps (iv) amplifying the amplicon to produce an amplification product; and (v) detecting the amplification product; wherein detection of the amplification product allows detection of the analyte.

Applicant notes that the Examiner has included a copy of Kurn Figure 13 with his handwritten notes labeling the parts of the figure, which appear based on his interpretation of Kurn read in light of the specification of the instant application. The Examiner also listed the Kurn Figure 13 with his handwritten notes on the Notice of References Cited. Applicants point out that Figure 13 with the Examiner's handwritings is not prior art to the instant application under 37 CFR § 1.56, § 1.97 and § 1.98, and MPEP § 707.

Applicant submits that Kurn does not anticipate claim 1 and further dependent claims 3, 6, 8, 13, 14, 21 and 27, and does not anticipate claim 74 and further dependent claims 75-78. Therefore, Applicant respectfully requests withdrawal of the rejection of those claims under 35 U.S.C. § 102 (e).

#### **8. Conclusion**

In view of the above amendment, applicant believes the pending application is in condition for allowance. Should the Examiner feel that any issues remain, Applicant requests that the Examiner contact the undersigned so that the issues may be expeditiously addressed and prosecution of the instant application continue.

Applicant submits concurrently a request for a three-month extension of time under 37 C.F.R. § 1.136 and the accompanying fee. Please charge our Credit Card in the amount of \$1,050.00 covering the fee set forth in 37 C.F.R. §§ 1.17(a)(3) and 1.136(a). Credit Card Payment Form SB-2038, with a signature from an authorized cardholder, is enclosed for payment of the extension of time fee. In the event that any additional extension of time is


Application No. 10/826,654  
Amendment dated June 16, 2008  
Reply to Office Action issued December 14, 2007

Docket No.: P-6041 020187.0208PTUS

necessary to prevent the abandonment of this patent application, then such extension of time is petitioned. The U.S. Patent and Trademark Office is authorized to charge any additional fees that may be required in conjunction with this submission to Deposit Account No. 50-2228, under Order No. 020187.0208PTUS from which the undersigned is authorized to draw.

Dated: June 16, 2008

Respectfully submitted,

By   
Therese M. Finan  
Registration No.: 42,533  
PATTON BOGGS LLP  
8484 Westpark Drive, 9th Floor  
McLean, Virginia 22102  
(703) 744-8069  
(703) 744-8001 (Fax)  
Attorney for Applicant

Attachment: Replacement Sheet